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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,057	02/26/2002	Antoine F Carpentier	249326USOX PCT	4658

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
10/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/937,057	CARPENTIER, ANTOINE F	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-76,78-93* is/are rejected.

7)☒ Claim(s) *77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 8-1-07.

Claims 70-93 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-1-07 has been entered.

Election/Restrictions

Newly submitted SEQ ID Nos. 18, 19 and 47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These sequences were added to the other sequences previously listed in claim 65 of the previous claim set, examined in the prior Office action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, SEQ ID Nos. 18, 19 and 47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al.

Clark et al teach an (inherently immunostimulatory) oligonucleotide between 20 and 100 nucleobases in length comprising nucleotides 9-16 of SEQ ID No. 9, which oligonucleotide is optionally double or single stranded, and which occur in a non-methylated state in vitro and in cells (see Accession No. BI881470 of Clark et al).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 70-76, 78-83, 89-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (USPN 6,562,798).

Schwartz (USPN 6,562,798) teaches compositions comprising immunomodulatory oligonucleotides comprising the motif 5' purine-purine-CpG-pyrimidine-pyrimidine 3' which are single or double stranded and which are deoxyribonucleotides, which oligonucleotides optionally further comprise 5-bromocytosines and phosphorothioate modifications for enhancing stability and immunomodulatory capabilities, and which compositions additionally comprise colloidal dispersions systems, encapsulating agents, polymers and affinity moieties for enhancing target cell uptake, and pharmaceutically acceptable carriers (see entire document, esp. abstract, col. 4, 8-12, col. 25, including Table 1, claims 1, 9-13, 16-19, 23-24, 42, 51, 61 and 67).

It would have been obvious to one of ordinary skill in the art to design the immunomodulatory oligonucleotide comprising the well known motif 5' purine-purine-CpG-pyrimidine-pyrimidine 3' and with two additional bases (including the purines, AT) to provide the immunomodulatory oligonucleotide AACGTTAT because the basic motif comprising 5' purine-purine-CpG-pyrimidine-pyrimidine 3', comprising unmethylated CpG's, was well known in the art to produce immunomodulatory effects in organisms and placing two nucleotides on the 3' end would have been a matter of design choice.

One of ordinary skill in the art would have expected the two additional nucleotides on the 3' end would not diminish the immunomodulatory effects of any oligonucleotide comprising the immunomodulatory motif described above and it would require routine experimentation to design and test the addition of these two residues on the oligonucleotide for immodulatory activity.

One of ordinary skill in the art would have found it obvious to incorporate the well known modifications including phosphorothioate internucleotide linkages and 5-bromo cytosine into the oligoncucleotide because the technology to do so was well known in the art and these modifications were known to enhance oligonucleotide stability and immunomodulatory activity of CpG containing oligonucleotides, as taught previously by Schwartz. One of ordinary skill in the art would have been motivated to compose the compositions with the components claimed, including colloidal dispersion systems and cell target agents because these were well known to enhance target cell uptake in vitro and in vivo and one of ordinary skill in the art would have expected these compositions to be useful for enhancing oligonucleotide uptake by target cells. It would have been obvious to increase the number of immunomodulatory motifs in an oligonucleotide to enhance the immunomodulatory capability of oligonucleotides bearing this minimal motif, with or without additional nucleotides on the 3' end, because additional CpG motifs were well known to provide for additive immunomodulatory capabilities in vivo at the time the instant invention was made.

For these reasons, the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 84-88 and 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6-9 of U.S. Patent No. 7,108,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of treating cancer comprising the administration of a compositions comprising an oligonucleotide between 20-100 nucleobases in length and comprising SEQ ID No. 51.

Allowable Subject Matter

Claim 77, drawn to SEQ ID Nos. 9, 10, 16, 21, 31, 33, 34 and 35, appear free of the prior searched and of record. Claim 77 is objected to for including non-elected sequences (SEQ ID Nos. 18, 19 and 47).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
9-28-07